

REMARKS

Claims 1 and 3-24, as amended, appear in this application for the Examiner's review and consideration. Claim 1 has been amended to incorporate features from claim 2, which has been canceled. Accordingly, claims 3 and 4 have been amended to depend from claim 1 instead of claim 2. Claim 1 has been further amended to clarify that the composition is adapted to be applied to the area on the skin after micro-channels have been generated, the support for which is inherent in the prior wording of the claim and is expressly found in paragraph [0087] of the published application. Claim 1, as well as claim 14, has been amended to further clarify that the composition is devoid of permeation enhancers, the support can be found at paragraphs [0015], [0054] and [0056] of the published application. Claim 14 has been further amended to include features of the apparatus, the support for which is found at paragraphs [0021] and [0022] of the published application. Claim 24 has been amended to correct informalities. Two new figures, namely Figures 9 and 10, are submitted to show the apparatus as recited in claim 1 as amended, which comprises an electrode cartridge and a main unit containing electrical contacts through which the electrical energy from the main unit is transferred to the electrode cartridge. Support for the drawings can be found at paragraphs [0021], [0022], [0059] and [0060] of the published application. Since no new matter is introduced by these changes, the amendment should be entered at this time to reduce the issues for appeal and place the claims in condition for allowance.

The Examiner states in the office action that the declaration previously submitted is defective for failure to properly identify the specification with the international application number and the international filing date. Applicants will submit a new declaration with all the required information as soon as possible.

Claim 24 is objected to because of informalities. In response, the word "wrinkles" has been amended to "wrinkles". Therefore, the objection is overcome and should be withdrawn.

Claims 1-3, 5-7, 9, 10, 12-17, 19, 20 and 22-24 are rejected under 35 U.S.C. 102(b) as being unpatentable over U.S. Patent No. 6,302,874 to Zhang et al. (referred to hereafter as "Zhang"). Zhang teaches applying an electric pulse to the surface of a region of skin substantially contemporaneously with application thereto a composition comprising L-ascorbic acid (col. 3, lines 61-64 and col. 5, lines 31-35 of Zhang). Although the term "substantially contemporaneously" in Zhang means that the electric pulse and the composition are applied to

the region of skin to be treated reasonably close together in time, Zhang explicitly teaches that the composition preferably is administered prior to or concurrently with electropulsing (col. 7, lines 14-18 of Zhang). Zhang further teaches that the electric pulse has sufficient strength and duration to topically deliver an effective amount of the L-ascorbic acid to the region of skin (col. 9, lines 1-9 of Zhang). Example 2 of Zhang clearly demonstrates that a cosmetic composition is first applied to the skin and then pulsing is performed (col. 18, lines 11-23 of Zhang). In contrast, the claims of the present invention as amended recite that the cosmetic or dermatological composition is adapted to be applied to the area on the skin after the at least one micro-channel is generated, namely after the electrical energy has been applied (see also paragraphs [0031]-[0032], [0082]-[0083] and [0087] of the published application). Moreover, it should be emphasized that the electrical energy applied to the electrodes of the present invention is aimed at creating micro-channels only, not for topically delivering the cosmetic agent to the region of skin as taught by Zhang, because the cosmetic composition is applied after micro-channels have been generated (see paragraphs [0031]-[0032] and [0082]-[0083] of the published application). Moreover, Zhang teaches away from the present invention by using permeation enhancers to enhance the permeability of the stratum corneum (col. 8, lines 32-42 of Zhang). In contrast, claim 1 as amended specifically recite that the cosmetic or dermatological composition is devoid of permeation enhancers.

Furthermore, Zhang teaches a device and a method for electroporation to create transient aqueous pathways (pores) in lipid bilayers (col. 2, lines 65-66; col. 4, lines 19-21; col. 10, lines 34-35 of Zhang). Zhang also teaches that during an electric pulse, skin resistance drops within microseconds and this drop in skin resistance exhibits either complete or partial reversibility within minutes or longer (col. 3, lines 21-24 of Zhang). Zhang further discloses that at relatively low voltages the drop of skin resistance can be attributed to electroporation of the appendages (e.g., sweat glands and hair follicles), while at high voltages, electroporation of the lipid corneocyte matrix leads to an additional drop of skin resistance (col. 3, lines 24-29 of Zhang). In contrast, the present invention discloses ablation of stratum corneum to generate micro-channels in a region of skin of a subject (see paragraphs [0019], [0033], [0056] and [0067] of the published application), which is not taught or suggested by Zhang. It should be emphasized that the micro-channels disclosed in the present invention cannot be generated by electroporation of the lipid bilayers. The micro-channels of the present invention are large pathways extending

from the surface of the skin through all or a significant part of the stratum corneum (paragraph [0048] of the published application). The diameter of the micro-channels is typically of about 10 to about 100 microns and a depth of about 20 to about 300 microns (paragraph [0062] of the published application). As the depth of the stratum corneum in human skin is approximately 100 microns, the micro-channels generated by the apparatus of the present invention can extend even beyond the stratum corneum. Thus, the micro-channels disclosed in the present invention are large pathways, larger than the pores created in the lipid bilayers by electroporation. The present claims as amended further clarify the differences between the electropores of Zhang and the micro-channels of the present invention by reciting that the apparatus ablates the stratum corneum to generate micro-channels. In view of the foregoing, Zhang does not teach or suggest the present invention as claimed and rejection over Zhang should be withdrawn.

Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. US 2002/0038101 to Avrahami et al. (referred to hereafter as “Avrahami”). Avrahami discloses a device for enhancing transdermal movement of a substance which comprises: (a) a skin patch, with at least two electrodes in contact with the skin of a subject; and (b) a control unit, coupled to the patch, which causes a current to pass between the electrodes through the stratum corneum epidermidis, in order to generate at least one micro-channel in the stratum corneum to enable or augment transdermal movement of the substance (paragraph [0017] of Avrahami). Additionally, Avrahami discloses that the patch comprises two or more electrodes (paragraph [0170] of Avrahami). Thus, the patch according to Avrahami is an electrode patch (paragraphs [0017], [0173] and Figs. 1A and 1B of Avrahami) capable of generating micro-channels while containing the substance to be delivered, which is coupled by electrical contacts to the control unit. In contrast, the present invention discloses an electrode cartridge, not an electrode patch as taught by Avrahami, that generates micro-channels in the skin of a subject (paragraphs [0021] and [0059] of the published application). The composition of the present invention is not contained within the electrode cartridge but rather applied on the region of the skin after micro-channels have been generated by the main unit and electrode cartridge of the present invention (paragraphs [0032] and [0083] of the published application). Thus, the electrode cartridge of the present invention has a distinct and different structure than the electrode patch disclosed by Avrahami. Therefore, Avrahami does not teach or suggest the present invention as claimed and the rejection over Avrahami should be withdrawn.

Claims 1, 5, 8, 10, 11, 14, 15, 18, 20, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,477,410 to Henley et al. (referred to hereafter as “Henley”). Henley teaches a self-powered hand-held electrokinetic delivery device for self-administering a medicament, which electrokinetically drives the medicament from an applicator into the treatment site (col. 6, lines 50-54 of Henley). Henley further teaches that preferably, a low-cost throwaway single-use applicator is used to facilitate the flow of medicament into the skin under the influence of the electromotive force supplied to the medicament contained in the applicator by the self-powered hand-held wireless device (col. 6, lines 55-59 of Henley). Henley teaches that the applicator 40 is preferably applied to the device by aligning the pad 44 with the active electrode 24 on the end of housing 12 (col. 20, lines 49-51 of Henley). Henley further teaches that the active electrode 24 is also in electrical contact with the medicament containing pad 44 (col. 21, lines 1-3 of Henley). According to Henley, upon contact, electrical current flows between the active electrode 24 in the handpiece, through the medicament-containing pad 44 into the treatment site. Consequently, the medicament is electomotively transported through the individual’s skin or mucocutaneous membrane, thus enhancing local delivery of the medicament to the treatment site (col. 21, lines 5-12 of Henley). In contrast, the present invention as claimed discloses an apparatus that generates micro-channels in a region of skin of a subject and a cosmetic or dermatological composition adapted to be applied to the region of skin after micro-channels have been generated. There is no electromotive force that drives the cosmetic agent into the skin. In addition, as the cosmetic composition is applied after micro-channels have been generated, there is no electrical contact between the apparatus and the composition. Base on the forgoing, Henley does not teach or suggest the present invention and the rejection over Henley should be withdrawn.

Accordingly, it is believed that the entire application is believed to be in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of this application.

Respectfully submitted,

Date: 8/28/08

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